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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,483	01/30/2004	Robert E. Clark	Duby/Clark-CIP	8748
22536 7590 08/14/2007 KNECHTEL, DEMEUR & SAMLAN 525 W. MONROE STREET, SUITE 2360 CHICAGO, IL 60661			EXAMINER HAND, MELANIE JO	
			ART UNIT 3761	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/769,483

Applicant(s)

CLARK, ROBERT E.

Examiner

Melanie J. Hand

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-17 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-17, 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

The affidavit filed on April 27, 2007 under 37 CFR 1.131 is sufficient to overcome the Nitsch reference.

Response to Arguments

Applicant's arguments with respect to claims 1-8, 10-17 and 19-22 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8, 10, 11, 13-15, 17 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (U.S. Patent No. 4,737,140).

With respect to **claim 1**: Lee teaches a fluid irradiation apparatus 10 for the modification of viruses and bacteria, comprising: a housing having an exterior side and an interior side, the interior side further defining an enclosure;
an irradiation station 513 affixed to the housing (Figs. 1, 4, Col. 6, lines 14-17); means 22 for receiving the fluid transported and irradiated through the cuvette (Col. 7, lines 26-29); means 23 for enclosing the cuvette and irradiation station when the fluid irradiation apparatus is in use for minimizing the escape of ultraviolet light radiation; and means 216 for energizing the fluid

irradiation apparatus (Col. 6, lines 60-63). The means 216 taught by Lee is considered herein to be an equivalent of the disclosed means in accordance with 35 U.S.C. 112, sixth paragraph.

Lee teaches tubing 24 but does not explicitly teach a cuvette. However Lee fairly suggests a cuvette positioned across the irradiation station, as Lee teaches that such cuvettes for holding cell-containing samples such as blood to be irradiated are known in the art (Col. 2, lines 3-6). Thus it would be obvious to one of ordinary skill in the art to modify the device of Lee so as to contain a cuvette with a reasonable expectation of success.

Lee teaches at least two ultraviolet light sources 400 (Fig. 2, Col. 6, lines 60-63, Col. 7, lines 10-12) but does not teach that they are positioned adjacent to a cuvette. However, as stated supra, since Lee fairly suggests a cuvette for holding samples to be irradiated, Lee also fairly suggests a device in which the ultraviolet sources 400 are positioned adjacent said cuvette.

Lee does not explicitly teach an ivac bottle for drawing and transporting fluid through the cuvette. However the disclosed means for drawing and transporting fluid through the claimed cuvette includes either a pump or a bottle, and Lee teaches a peristaltic pump 12 for drawing and transporting blood through tubing 24 (or a cuvette). The pump of Lee is thus considered an equivalent of the pump in accordance with 35 U.S.C. 112, sixth paragraph.

With respect to **claim 2**: Lee fairly suggests a spectrophotometer cuvette, which is known in the art as being manufactured from quartz crystal material (see U.S. Patent No. 4,979,821 to Schutt et al, Col. 6, lines 66-68).

With respect to **claim 3**: Lee fairly suggests a spectrophotometer cuvette, which is known in the art as being made of a durable plastic material. (see U.S. Patent No. 4,979,821 to Schutt et al, Col. 6, lines 66-68)

With respect to **claim 4**: Lee teaches that the at least two ultraviolet light sources 400 are, when in use, positioned on opposite sides of irradiation panel 513. The suggestion to modify the device of Lee so that the sources are on opposite sides of a cuvette is stated *supra* with respect to claim 1.

With respect to **claim 5**: Lee does not teach that one ultraviolet light source is mounted in the enclosure and the other ultraviolet light source is mounted in a cover. However applicant has not assigned sufficient criticality to this limitation, therefore it would be obvious to one of ordinary skill in the art to modify the device of Lee so as position the sources 400 such that one ultraviolet light source is mounted in the enclosure and the other ultraviolet light source is mounted in a cover with a reasonable expectation of success. It has been held that rearranging elements of an invention involves only routine skill in the art. See *In re Japikse*, 86 USPQ 70 (CCPA 1950)

With respect to **claim 6**: The at least two ultraviolet light sources 400 are calibrated in the UVA light transmission band width. (Col. 7, lines 9-12)

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With respect to **claim 7**: The at least two ultraviolet light sources 400 are calibrated in the UVA light transmission band width, thus they are necessarily calibrated in the range of between 320-400 nm, which overlaps the claimed range of 40 and 400 nano meters. (Col. 7, lines 9-12)

With respect to **claim 8**: The means 12 for drawing and transporting fluid through the cuvette is by a peristaltic pump. (Col. 6, lines 46-50)

With respect to **claim 10**: Lee does not teach that the means 22 for receiving the fluid transported and irradiated through the cuvette is a bottle, however, in accordance with 35 U.S.C. 112, sixth paragraph, the container 22 taught by Lee is considered an equivalent of the claimed bottle.

With respect to **claim 11**: The means 23 for enclosing the cuvette and irradiation station when the fluid irradiation apparatus is in use is considered herein to be its cover.

With respect to **claim 13**: Lee teaches a fluid irradiation apparatus 10 for the modification of viruses and bacteria contained in fluid, comprising: a housing having an exterior side and an interior side, the exterior side further defining an aperture 209 and the interior side further defining a hollow center (Figs. 1,2); a first ultraviolet light source 400 located within the hollow center of the interior side of the housing and positioned parallel to the cuvette; a cover having an exterior side and an interior side, the interior side further defining a chamber (Fig. 1); a second ultraviolet light source 400 located within the chamber; means 22 for receiving the fluid

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transported through the cuvette; means 12 for transporting the fluid through the cuvette into the means 22 for receiving the fluid (considered herein to render the claimed means unpatentable in accordance with 35 U.S.C. 112, sixth paragraph); whereby, the fluid transferred through the same cuvette is irradiated in at least two separate instances by both the first and second ultraviolet light sources. Applicant teaches that the means for returning the fluid back through the cuvette from the means for receiving the fluid is a process and since Lee teaches either the specific elements or equivalents thereof in accordance with 35 U.S.C. 112, sixth paragraph, Lee teaches a means for returning fluid back through the cuvette (Col. 7, lines 13-33).

Lee teaches flat plate irradiator 513 positioned across substantially the surface area of the aperture 209 and aligned in a substantially parallel relationship with the housing, but does not teach a cuvette. However Lee fairly suggests a cuvette positioned across the irradiation station, as Lee teaches that such cuvettes for holding cell-containing samples such as blood to be irradiated are known in the art (Col. 2, lines 3-6). Thus it would be obvious to one of ordinary skill in the art to modify the device of Lee so as to contain a cuvette with a reasonable expectation of success.

Lee does not teach a lens for covering the second ultraviolet light source. However lenses of many varieties intended to shield ultraviolet radiation (e.g. eyeglasses) or provide a barrier between an ultraviolet source and another entity are widely known. Thus it would be obvious to one of ordinary skill in the art to modify the device of Lee so as to have a lens covering the second ultraviolet light source

With respect to **claim 14**: The fluid irradiation apparatus 10 further comprises a means 12 for drawing the fluid through the cuvette.

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With respect to **claim 15**: The fluid irradiation apparatus 10 further comprises a means 23 for enclosing the plate 513 when the fluid irradiation apparatus is in use in accordance with 35 U.S.C. 112, sixth paragraph. Lee does not teach but fairly suggests a cuvette. The suggestion to modify the device of Lee is stated *supra* with respect to claim 13.

With respect to **claim 17**: Lee does not teach a faceplate that is fitted within the aperture in the exterior side of the housing. However since Lee teaches an ultraviolet source and the use of faceplates to shield an ultraviolet light source from another entity are widely known in the art (e.g. eyeglasses or sunglasses), it would be obvious to one of ordinary skill in the art to modify the device of Lee so as to have a faceplate. Such a faceplate would necessarily fit within the aperture 209 since the UV sources 400 extend along the entire length of the housing in cavity 503.

With respect to **claim 19**: Lee teaches that the at least two ultraviolet light sources 400 are, when in use, positioned on opposite sides of irradiation panel 513. The suggestion to modify the device of Lee so that the sources are on opposite sides of a cuvette is stated *supra* with respect to claim 13.

With respect to **claim 20**: Lee teaches a method for modifying viruses and bacteria from fluid in the body, comprising the steps of: (a) providing a fluid irradiation apparatus 10 consisting of a housing and an irradiation station in the housing; (b) removing fluid from the body and depositing the fluid into a conduit in the form of a serpentine pathway 512 in cavity 503; (c) transporting the removed fluid from the body along the conduit 512 and into a flat panel

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irradiator 513; (d) irradiating the removed fluid at the irradiation station within the irradiator by at least two ultraviolet light sources 400; (e) transporting the irradiated fluid from the irradiator 513 along the conduit 512 and depositing the irradiated fluid into a container 22. (Col. 10, lines 44-46)

Lee does not explicitly teach step (c) because Lee does not teach a cuvette. However Lee fairly suggests a cuvette positioned across the irradiation station, as Lee teaches that such cuvettes for holding cell-containing samples such as blood to be irradiated are known in the art (Col. 2, lines 3-6). Thus it would be obvious to one of ordinary skill in the art to modify the device of Lee so as to contain a cuvette with a reasonable expectation of success.

Lee also does not teach steps (f) through (j). However Lee teaches cycles of irradiation of blood from a patient between which an irradiated blood portion from container 22 is returned to the patient via a centrifuge 13 until the desired amount of leukocyte enriched blood is achieved, therefore it would be obvious to one of ordinary skill in the art to modify the method taught by Lee so as to include the step of removing the irradiated fluid from the container 22 and depositing the fluid back into the conduit 512 via centrifuge 13 to ensure that a desired volume of leukocyte-enriched blood is obtained. (Col. 5, lines 48-67)

With respect to **claim 21**: Lee fairly suggests the additional step of directing ultraviolet radiation from the at least two ultraviolet light sources 400 at a cuvette. The suggestion to modify the device of Lee so as to contain a cuvette and to include the method step of directing ultraviolet radiation from the at least two ultraviolet light sources 400 at a cuvette is stated *supra* with respect to claim 20, as the step set forth in claim 21 is part of the irradiation cycle explicitly taught by Lee.

With respect to **claim 22**: Lee teaches a method for modifying viruses and bacteria from fluid in the body, comprising the steps of: (a) transporting fluid, namely blood, through a conduit 512; (b) providing a plurality of ultraviolet light sources 400; (c) irradiating the fluid in conduit 512 as it passes the plurality of ultraviolet light sources 400 to produce a first irradiated fluid.

Lee does not explicitly teach all of the limitations of steps (a) - (c) because Lee does not teach a cuvette. However Lee fairly suggests a cuvette positioned across the irradiation station, as Lee teaches that such cuvettes for holding cell-containing samples such as blood to be irradiated are known in the art (Col. 2, lines 3-6). Thus it would be obvious to one of ordinary skill in the art to modify the device of Lee so as to contain a cuvette with a reasonable expectation of success.

Lee does not teach but fairly suggests step (e), i.e. irradiating the first irradiated fluid as it passes the plurality of ultraviolet light sources a second time to produce a second irradiated fluid, because Lee teaches cycles of irradiation. Therefore it would be obvious to one of ordinary skill in the art to modify the method taught by Lee so as to include the step of removing the irradiated fluid from the container 22 and depositing the fluid back into the conduit 512 via centrifuge 13 to ensure that a desired volume of leukocyte-enriched blood is obtained. (Col. 5, lines 48-67)

Lee also does not explicitly teach step (d), i.e. reversing the directional flow of the fluid to pass back through the same cuvette. However since Lee teaches several cycles or pass-throughs of irradiated blood to reduce treatment time and teaches a pump that is capable of pushing blood through the apparatus, it would be obvious to one of ordinary skill in the art to modify the method of Lee so as to include the step of reversing the directional flow of the fluid to

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pass back through the same cuvette to reduce treatment time. (Col. 3, lines 4-10, Col. 5, lines 48-67)

Claims 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al ('140) in view of Einstein (U.S. Patent No. 6,951,548).

With respect to **claim 12**: The fluid irradiation apparatus 10 further comprises an on/off power switch 19, a pump speed control assembly, and ultraviolet light control contacts 216.

Lee does not teach an on/off pump control switch or an ultraviolet light control switch. Einstein teaches a number of switches 76 provided to automate different processes of a blood irradiating apparatus 10 for example, the activation or intensity of individual lamps (i.e. a UV light control switch) and the flow velocity of the blood through the cuvettes 200, 300 (i.e. an on/off pump control switch). Since the devices of Lee and Einstein seek to solve a similar problem in the art (i.e providing a means of controlling pump speed, power and ultraviolet light sources), it would be obvious to one of ordinary skill in the art to modify the device of Lee so as to substitute a pump speed switch for the pump speed control and to substitute the ultraviolet light source contact with switches with a reasonable expectation of success.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

July 18, 2007

SUPERVISOR/PRIMARY EXAMINER
TATYANA ZALUKAEVA
SUPERVISOR/PRIMARY EXAMINER
